STUDY TITLE: A Randomized, Double-Blind, Placebo-Controlled Clinical Trial to Evaluate the Efficacy of Dupilumab (ANTI-IL4RA) in Subjects with Eosinophilic Gastritis

Investigator:
<INSERT PI NAME>

Contact Info:
<INSERT SITE CONTACT NUMBER>

Protocol #:
CEGIR 7810

Drug Name:
Dupilumab

Funding: National Institutes of Allergy and Infectious Disease (NIAID), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Office of Rare Diseases Research (ORDR), National Center for Advancing Translational Sciences (NCATS), and Regeneron Pharmaceuticals, Inc.

Key Information:

The following is a short summary of this study to help you decide whether to be a participant in it. More detailed information about the study is listed later in this form. This document does not replace the discussion you should have with the research team about this study including having any questions or concerns answered.

If you are 18 years and older: This is a consent form. It explains this research study. If you decide that you want to be in this research study, then you will sign this form to show that you agree to be part of this study. If you sign this form, you will receive a signed copy of it for your records.

Parents/Guardians: You have the option of having your child or teen join this research study. This is a parental permission form. It explains this research study. If you decide that your child can be in this study, you will sign this form to show that you agree. If you sign this form, you will receive a signed copy for your records.

COMBINED Parental Permission/Assent: If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may also be required. When we say "you" in this form, we mean you or your child; "we" means the study doctor and other staff.

Taking part is this research study is voluntary. We will explain this research study to you. You may ask questions.

- Taking part in this study is your decision.
- You may change your mind at any time.
- You will be given a chance to speak with your doctor and the study clinicians.
- You may stop the study at any time.
- You will be given a copy of this consent form for your records.

If you agree to participate in this study, no study-related tests or procedures will be performed until you sign and date this form. To protect your safety, rights, well-being and dignity, all research is reviewed by an independent group of people called an ethics committee/institutional review board. This study has been given approval/a favorable opinion.

Reason for the study:

This study is being conducted to determine the safety and effectiveness of a study drug called dupilumab in adolescents and adults with eosinophilic gastritis (EG) with or without esophageal and/or duodenal eosinophilia. In this study, dupilumab is considered an experimental drug because it has not been approved by the US Food and Drug Administration (FDA) to treat EG. Dupilumab is approved by the FDA for the treatment of atopic dermatitis, asthma, and chronic rhinosinusitis but not eosinophilic gastrointestinal diseases. We want to see how people with EG

or EGE feel while taking this drug and if dupilumab helps improve the inflammation in the stomach of people with EG.

You are being asked to be in this research study, because you have been diagnosed with eosinophilic gastritis (EG) and are ≥ 12 and < 71 years old. Some patients with EG also have involvement of other gastrointestinal parts, referred to as eosinophilic gastroenteritis (EGE). EGE patients will also be allowed to participate in this study. EG and EGE are inflammatory diseases involving the stomach or several gastrointestinal locations including the esophagus, stomach, and small intestine respectively. In order to participate you must meet certain criteria and sign this consent form.

Procedures:

This study has a double-blind and open label treatment period. "Double-blind" means that neither you nor the study doctor will know if you are receiving dupilumab or placebo. A placebo is an inactive substance, that looks like the medicine, but which contains no medicine. Once you complete the double-blind period, you may join the open-label portion of the study. During the open-label period you will receive dupilumab.

Your participation in this study may last up to 56 weeks including the screening period (up to 8 weeks), double-blind study treatment period (12 weeks), open label study treatment period (24 weeks), and a follow-up period (12 weeks). Visits are every 4 – 6 weeks with the exception of the first two visits which are every two weeks. Clinics visits will take 1 to 2 hours. Endoscopy visits will take up to 4 hours. You may be asked to complete the following assessments and procedures that are specific to research:

- Questions about symptoms on an electronic diary
- Endoscopy with biopsies
- Subcutaneous (SC) injection (under the skin) of the study treatment
- Physical exam, vitals, height, and weight
- Blood and urine sample collections
- Medical history collections; and answer health-related questions
- Training on injection of study drug

More detailed information about the study procedures can be found under ***"(Detailed Procedures)"***

Risks to Participate:

The study drug may affect how different parts of your body work and cause side effects. The table below shows the most common and most serious side effects that researchers know about. We do not know all of the side effects that may occur.

Risks	
Most Common (> 10% of patients) • Conjunctivitis (pink eye) • Injection site reaction (pain, redness)	**Serious** • High blood eosinophils (1-10%) • Severe allergic reaction (<1%) • Serum sickness (<1%)

More detailed information about the risks of this study can be found under ***"(Detailed Risks)"***

Benefits to Participate:

You may or may not personally benefit from your participation in the study. However, your participation will provide information on the effects of dupilumab in people with EG and EGE. As a result, the information from this study might help others like you in the future.
If, during the course of the study, the study doctor learns information related to your health that may be clinically important, the study doctor may discuss this information and your options with you.

Other Options:

Participation in research is completely voluntary. Your decision to participate or not to participate will not affect the clinical care you receive. There are other treatments available if you decide not to be in the study.

Alternative Treatments

- Elimination diet
- Steroids
- Esophageal dilation

If you have any questions about alternative treatments, please ask your study doctor.

Cost to Participate:

There will be no charge to you or your health insurance company for any costs which are directly related to this study including endoscopy, research biopsies, study visits to the hospital and laboratory tests.

Payment:

You will receive $95.00 for each completed endoscopy visit in the screening and double-blind portion of the study. You will receive $50.00 for each of the remaining visits that you complete in the double-blind portion of the study.

You will receive $150.00 for completing the endoscopy visit in the Open Label Extension (OLE), which means you will be treated with study drug, no placebo will be given in this portion of the study. After you complete the OLE clinic visits, you'll receive $75.00 for each visit. Additionally, you'll receive $50.00 for each completed telephone visit.

You will be reimbursed for any reasonable travel and expenses (if applicable), after receipts for the payments are provided to the study team, and in agreement with the study doctor. This includes flights, rail travel, ground transportation service, travel by own car (mileage), hotel and meals. A handout will be provided with additional reimbursement details.

Insert site specific details for payment

Additional Study Information:

The following is more detailed information about this study in addition to the Key Information.

If I have Questions or would like to know about:

Who to talk to…	**You can call …**	**At …**
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	<INSERT SITE PI>	Phone: <CONTACT NUMBER>
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	<INSERT SITE COORDINATOR>	Phone: <CONTACT NUMBER>
• Your rights as a research participant	**Institutional Review Board** This is a group of scientists and community members who make sure research meets legal and ethical standards.	Phone: <CONTACT NUMBER>

This study is directed by Dr. Marc E. Rothenberg M.D, Ph.D., a researcher at Cincinnati Children's Hospital Medical Center (CCHMC), the Division of Allergy and Immunology with collaboration from the Division of Gastroenterology, Hepatology, and Nutrition at CCHMC. Dr. Rothenberg is responsible for the medical supervision of this research. <INSERT LOCAL PI NAME> is responsible for the medical supervision of this study at <INSERT SITE NAME>. If you have general questions about your rights as a research participant in this research study, or questions, concerns, or complaints about the research, you can call the Institutional Review Board as listed above. You can also call the CCHMC Institutional Review Board at 513-636-8039.

Total number of participants:

This study will include approximately 40 adolescents and adults across all research centers in the United States.

Detailed Procedures:

Your participation in this study may last up to 56 weeks (approximately 14 months).

There are two main parts to this study: the randomized, double-blind, placebo-controlled study treatment phase and open-label extension period.

"Randomized" means that the group you will be placed in is decided by chance, similar to drawing numbers out of a hat or flipping a coin. A placebo is an inactive substance that looks like a medicine, but does not contain medicine. You will have an equal chance of receiving the experimental study drug or placebo; specifically, you will have a 50% chance of receiving the study drug and a 50% chance of receiving the placebo.

"Double-blind" means that neither you nor the study doctor will know which study treatment group you have been assigned (i.e. who is receiving dupilumab or placebo). This is done to make sure the results of the study cannot be influenced by anyone. If there is an urgent need, the study team can find out quickly which study medicine you are receiving.

"Open-label" means all participants will receive the study drug, no placebo will be given in this portion of the study.

Once you complete the double-blind study treatment portion of the study, you will be offered the opportunity to screen for entry into the open-label study treatment portion of the study. In this open-label study treatment portion of the study, you will receive dupilumab.

This study has different sections; they are:

Screening Period: Up to 8 weeks

- You will be asked to read and sign this consent form.
- Endoscopy with biopsy will be performed for study eligibility purposes.
- You will be asked questions about you and your medical history.

Double-blind Treatment Phase: 12 weeks

- You will have 5 visits to the clinic at weeks 0, 2, 4, 8 and 12.
- You will receive an injection of the study treatment at week 0.
- You or your caregiver will be trained in administration of the study treatment at weeks 0, 2 and 4.
- You or your caregiver will administer the injection at weeks 2, 4, 6, 8 and 10 and if you continue into the open-label extension period of the study, at week 12. At some clinic visits, you have the option for medical staff to administer the injection.
- Study eligibility will be assessed at week 0 and if you decide that you'd like to continue into the open label extension period, study eligibility will be reviewed again at week 12.
- At week 12, an endoscopy with biopsy will be performed.

Open-Label Extension Period: 24 weeks

- At weeks 2, 12 and 24, you will have clinic visits.
- At weeks 6 and 18, you will have telephone visits.
- You or your caregiver will administer dupilumab injections every 2 weeks at weeks 2, 4, 6, 8, 10, 12, 14, 16, 18, 20 and 22. At clinic visits, you have the option for medical staff to administer the injection.
- At weeks 4 and 16, you will need to have a blood draw done at a local laboratory and have the results sent to your study team.
- You will receive an endoscopy with biopsy at the final week 24 clinic visit.

Follow-Up Period: 12 weeks

- After you complete either the double blind study treatment phase or the open-label extension period of the study, you will be followed for 12 weeks.
- You will have a telephone visit and be asked questions about how you've been feeling since the last dose of study drug or placebo.

Other procedures that will be included in study visits:

- Study questionnaires. The questionnaires will ask you about your symptoms and quality of life. You will be asked to complete these questionnaires several times throughout the study.
- Collection of information on your current medications and diet.
- A physical examination.
- Measurement of your vital signs: height, weight, blood pressure, heart rate, breathing rate and body temperature.
- If you are a female capable of bearing children, a urine or blood pregnancy test.
- Collection of blood samples from a vein in your arm for clinical laboratory tests to evaluate your EG and health; if you are a female, we will check your blood to see if you have the ability to become pregnant.
- Collection of blood for research purposes. Clinical lab and research blood will be taken every 2 to 6 weeks. The amount of blood taken will vary from 5 ml (1 teaspoon) up to 45 ml (3 tablespoons).
- Provide urine for routine laboratory testing to evaluate your health.
- When you have an endoscopy we would like to have the doctor collect up to 20 to 24 research biopsies; a biopsy is a small piece of tissue from your esophagus, stomach and intestines.

Some tissue samples collected during an endoscopy will be used for genomic testing to help understand how dupilumab works. Some blood samples will also be used for genomic testing (see Genomic Testing Risk Section below). Other tissue samples will be used to determine expression of proteins and assess for potential biomarkers. Some blood samples will also be used for biomarker analysis.

You will be seen by study staff including study coordinators and study doctors, as well as medical staff.

Change of Mind/Study Withdrawal:

You may decide not to take part or to leave the study at any time.

If you no longer wish to receive injections, you be will be given the option to withdraw from all injection associated study procedures and continue to stay in the study to complete study questionnaires.

If you decide to leave the study completely and no longer wish to participate in any study procedures, there is no penalty or loss of benefits in your routine medical care or any other benefit(s) that you would otherwise be entitled to receive. We will follow you for 12 weeks after you leave the study and call you at the end of the 12 week period to ask you how you've been feeling. In addition, you should talk to your study doctor who will discuss future treatment and procedures for your continued care.

If you stop being in the research, data already collected may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

You may also be removed from the study without your consent at any time. Reasons why you may be removed from the study include, but are not limited to, the following:

- The study doctor feels it is not in your best interest to continue in this study.
- You are unable to complete required study treatments and examinations.
- If you experience unusual or serious side effects
- You need to take medicines to treat an exacerbation of your eosinophilic gastrointestinal disease/s.
- You need to take medicines that aren't allowed to be taken when participating in this study.
- You become pregnant or initiate breastfeeding.
- The study is stopped by the Institution, the Sponsor(s), or by the Food and Drug Administration (FDA) or other health authorities.

If you are removed from the study, your study doctor will contact you to discuss stopping procedures and your future care. The study doctor will also tell you about any new information that may affect your willingness to continue in this study.

Detailed Risks:

Dupilumab has been studied in more than 10,191 individuals in completed and on-going studies, including healthy volunteers, patients with atopic dermatitis, asthma, nasal polyps and eosinophilic esophagitis. In these studies, some patients were treated with dupilumab while others received placebo. In completed studies approximately 8,720 patients have received dupilumab, including children and adolescents with atopic dermatitis and asthma.

A side effect is an undesirable effect of a drug or medical treatment. In clinical studies of dupilumab in adults with atopic dermatitis, side effects reported more often in patients treated with dupilumab compared to those receiving placebo, and which were possibly related to dupilumab, are listed in the table below.

Most Common (more than 10% of patients)	**Common** (1 to 10% of patients)	**Rare** (<1% of patients)
Conjunctivitis: 'Pink eye' due to allergy, infection or other cause	Headache	Anaphylactic allergic reaction
Injection site reaction: Complaints of pain, itching, swelling, redness, etc. at the site of study drug injection	Oral Herpes: 'Cold sores'(also known as 'fever blisters') on the mouth and lips	Serum sickness like reaction, serum sickness: A type of reaction in which patients may develop symptoms including fever, skin rash, joint swelling, joint pain, muscle pain, headache, nausea, diarrhea, swollen glands and blurred vision
	Blepharitis: Inflammation (swelling and redness) of the eyelid	
	Eye pruritus: Itching in eye	
	Dry eye: Dryness of the eyes	
	Keratitis: Swelling and redness of the cornea (the outer layer of the eyeball)	
	Eosinophilia: Increase in a certain kind of white blood cells as detected in a blood test	

The higher risk of pink eye, inflammation of the eyelid or outer layer of eyeball, and herpes sores in dupilumab treated patients has been observed in atopic dermatitis patients and not in asthma patients. You should let your study doctor know about any new or worsening eye symptoms to the study doctor. If you develop pink eye (conjunctivitis) that does not resolve or if your signs and symptoms are suggestive of keratitis (swelling and redness of the cornea), inform your study doctor who may refer you to an ophthalmologist.

A higher frequency of nose-bleeding was observed in dupilumab-treated patients (7 of 30) compared to placebo-treated patients (2 of 30) in a completed nasal polyps study. Consult your doctor if the nose-bleeding is difficult to control.

The study drug and procedures in this research study may involve risks that are not possible to predict. You will be informed of any new risks that may be identified during the study. Below is a description of the risks we know about the study drug and each procedure. Please ask your study doctor or the research staff to explain any procedures or risks that you do not understand.

The following risks associated with receiving dupilumab may occur:

<u>Allergic Reaction Risk</u>

As with any drug, there is a slight chance that you may experience a local or generalized allergic reaction (also known as a hypersensitivity reaction), including anaphylactic reaction. An anaphylactic reaction can happen immediately (within minutes or hours) after taking study drug. Symptoms of an anaphylactic or other allergic reaction may include skin flushing, rash or hives, sneezing, runny nose, difficulty breathing, wheezing, a sense of choking, sudden change in blood pressure (causing dizziness or lightheadedness), swelling around the mouth, throat, or eyes, fast pulse or sweating, abdominal cramps, diarrhea, etc. The severity of this type of immediate reaction ranges from mild to severe. A mild reaction may progress to a more severe one, so you should contact the study personnel if you experience any new symptoms occurring within a couple of hours after study drug injection. You should not get dupilumab injection if you have had a generalized or serious or severe allergic reaction to dupilumab in the past or have a known allergy (hypersensitivity) to any part of this medication.

An anaphylactic or severe allergic reaction requires immediate medical treatment and could result in permanent disability or death if not treated promptly. If you believe you are having an anaphylactic or severe allergic reaction, you should immediately seek emergency medical treatment and alert the study doctor and study staff as soon as possible.

Another kind of hypersensitivity reaction called 'serum sickness' sometimes occurs days to weeks after study drug injection and it may cause complaints of fever, skin rash, swelling and pain in joints, muscle pain, swollen glands, headache, nausea, diarrhea and blurred vision.

Other Possible Risks

There is a risk that your underlying disease (EG), for which you are in this study, may not get better or may worsen during the study.

Dupilumab has not been studied as extensively in children as in adults. There might be some risks of dupilumab that are specific to children, which are currently unknown.

Dupilumab has not been studied in pregnant or breastfeeding women. There may be unknown risks or side effects to a pregnant woman, fetus, and/or nursing child/mother. You should not become pregnant or breast-feed while taking part in this study.

Based on the nature of dupilumab and how it works, other theoretical risks might include infections with parasites (e.g. intestinal worms) and an increased risk of cancer.

Also, it is possible that your body may develop antibodies to dupilumab. Formation of antibodies is a natural defense reaction of the body's immune system against the presence of foreign substances. These antibodies may sometimes work against your body, which could result in illness.

In a clinical study in adult patients with atopic dermatitis, dupilumab was shown to not interfere with the development of immune response to two non-live vaccines (Adacel and Menomune) that were tested in this study. These vaccines provide protection against infections specific to these vaccines. Dupilumab has not been tested with live virus vaccines.

Based on results from a research study in patients with atopic dermatitis, dupilumab is not expected to have an interaction with most of the drugs that are commonly prescribed by doctors. However, since data do not exist for every drug, it is possible that dupilumab may have some interaction with other drugs you are taking. Your doctor will review the current medications you are taking and discuss any known or potential interactions.

A temporary increase in a type of white blood cell called an eosinophil has been observed in atopic dermatitis studies. This increase was not associated with clinical symptoms. However, in asthma studies, this increase in blood eosinophils has rarely been associated with eosinophil related illnesses, which in some cases can be very serious. Please discuss with your study doctor if you have history of high blood eosinophil counts or an eosinophil related disorder or experience unexplained symptoms like numbness, tingling, weakness, rash and worsening cough or any new heart problems.

In one study of patients with moderate to severe asthma, more patients on dupilumab reported serious adverse events involving the heart than patients on placebo. A similar imbalance has not been observed in other dupilumab clinical studies.

Post-marketing information

Some additional side effects beyond those identified in clinical trials have been identified from reports received after dupilumab was placed on the market:

- Joint pain
- Angioedema (a condition that causes puffiness or swelling in the tissue under the skin; areas that may be affected include but are not limited to, the face, eyelids, mouth, tongue and hands)
- Ulcers on the cornea (the outer clear layer in front of the eyeball)

It is possible that there may be other side effects associated with dupilumab and injection devices which are unknown at this time, some of which may be serious or life-threatening. There is limited long-term safety data currently available with dupilumab. You should tell your study doctor or a member of the study staff about any new health problems that develop while you are in this study and about any new medications you started taking (including over-the-counter medication, herbal remedies, and non-prescription drugs).

If you have atopic dermatitis, asthma, and/or chronic rhinosinusitis with nasal polyposis symptoms, please do not adjust or stop your medications for these conditions without consulting with your study doctor.

Genomic Testing Risks

DNA is the substance that carries genetic (inherited) information and makes up your genes. DNA serves as the "instruction book" for cells and helps determine the characteristics of people (such as eye color). DNA may also determine whether a person is likely to get a certain disease, or how their disease may respond to drug treatment. RNA is the substance that is made based on the information contained in the genes.

As a part of this study, you will be required to provide tissue samples for genomic testing to help understand how dupilumab works in EG with or without esophageal or duodenal eosinophilia. RNA will be isolated from biopsy tissue samples for planned genomic analysis, including RNA sequencing. Additionally, RNA analysis will be conducted on blood samples.

It is possible that the RNA sequence that describes your child's genes could potentially identify him/her. Because the specific genes he/she has can make it more or less likely that they might develop certain medical conditions, knowledge of this information could also lead to unwanted psychological and financial consequences if it were released to you, your child, or any third party. There may also be other privacy risks that we have not foreseen.

There is a U.S. federal law called the Genetic Information Non-Discrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans and most employers to discriminate against your child based on his/her genetic information. This law does not protect against discrimination by companies that sell life, disability or long-term care insurance but the chances that your child's information would be released to these companies are very small.

Risks of Protocol Specified Medications

If you receive anesthesia for your endoscopy procedure, your study doctor will discuss the associated risks with you.

Risks of Study Procedures

- Endoscopy Procedure: The risks (<0.1%) associated with this procedure may include bleeding, a pinhole in your esophagus, stomach or intestines and/or infection.

- Biopsy Collection: May cause pain, bruising, bleeding, redness, low blood pressure, swelling, and/or infection at the site of the biopsies.

- Blood draws: Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn.

- Questionnaires: Some questions may be difficult or uncomfortable for you to answer. You will be given ample time to complete the questionnaires and may refuse to answer any questions that you are uncomfortable with.

There may be other risks that we do not know about yet.

Risks Associated with Pregnancy

If you are female, you must not be pregnant, breastfeeding, or become pregnant during this study and until 12 weeks after the last dose of study drug, because dupilumab has not yet been tested in pregnant or breastfeeding women. It is currently unknown if dupilumab may cause harm to you or your baby if you become pregnant.

If of child-bearing potential, you must agree to use a medically acceptable method of birth control from start of study until 12 weeks after the last dose of study drug. Please discuss acceptable birth control measures with your study doctor.

A pregnancy test will be performed prior to your enrollment and periodically during this study. For minors, pregnancy test results will be ***(insert institutional/state guidelines)***

If you become pregnant, you may no longer participate in this study and you must tell the study doctor immediately. Your study doctor will follow-up with you on the outcome of the pregnancy as required by the protocol

If you are a male, it is not necessary that you are on birth control or that your female partner, who is not participating in the research study, follow the acceptable birth control methods in this study.

Privacy:

Your medical and research records will be confidential to the extent permitted by law. Efforts will be made to keep your personal information private and to limit the use and disclosure of your personal information. However, we cannot guarantee complete confidentiality. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. The study monitors and the Food and Drug Administration will also be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access.

You will be identified by a code, and personal information from your records will not be released without your written permission. You will not be identified in any publication or in the sharing of your data about this study. After the study is completed, the data may be placed in a central storage location. These data will not include your name or other information that can identify you. The purpose is to make study data available to other researchers. Information from this study may be put into databases along with information from other studies. There are different kinds of databases; some are publicly accessible, and some are restricted. Anyone on the internet can access publicly accessible databases. Only researchers who apply and are approved can access restricted databases. Traditionally used identifying information about you (such as name, phone number, address) will NOT be included or shared with others.

Your privacy is important to us and we will use safety measures to protect your privacy. In spite of all the safety measures that we use, we cannot guarantee that your identity will never become known. Although your genetic information is unique to you, you share some genetic information with your children, parents, brothers, sisters, and other blood relatives. Consequently, it may be possible that genetic information from them could be used to help identify you. Similarly, it may be possible that genetic information from you could be used to help identify them.

While we will not use information that is traditionally used to identify you, people may develop ways in the future that would allow someone to link your genetic or medical information in our databases back to you. For example, someone could compare information in our databases with information from you (or a blood relative) in another database and be able to identify you (or your blood relative). It is also possible there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you. There may also be other privacy risks that we have not foreseen.

Investigators in this study will have access to your information. The tissue and blood samples that we collect from you may be shared with other outside researchers who are also studying EGIDs. There will be a code to link your tissue and blood samples with your name and other personal information but these will not be accessible to the other researchers.

The clinical information collected for this study will be stored at the Rare Diseases Clinical Research Network (RDCRN) Data Management and Coordinating Center (DMCC) and also sent to a Federal data repository. The data management center uses several layers of protection for the clinical data stored there. It meets all of the local and federal security requirements for research datacenters. Your information is stored only using a study identification number.

This research is covered by a **Certificate of Confidentiality** from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research participants.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the U.S. Department of Health and Human Services and/or the National Institutes of Health which is funding this project. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

Even with the Certificate of Confidentiality, the investigators continue to have ethical obligations to report child abuse or neglect and to prevent you from carrying out any threats to do serious harm to yourself or others. If keeping information private would immediately put you or someone else in danger, the investigators would release information to protect you or another person. The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as reports of child abuse and neglect, or harm to self or others.

A description of this study will be available on **http://www.ClinicalTrials.gov**. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

If injured while in the study:

<INSERT SITE SPECIFIC COMPENSATION POLICY>

Return of results:

Results of the research endoscopies will be returned to you and your treating physician. Other tests done on samples or images obtained in research studies are only for research and have no clear meaning for healthcare. If the research with your information or samples gives results that do have meaning for your health, the researchers will contact you and ask you if you would like

to know what they have found. You can say No to hearing about the results at that time if you desire.

AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH

<INSERT SITE SPECIFIC HIPAA LANGUAGE OR PROVIDE SEPARATE HIPAA AUTHORIZATION FORM FOR REVIEW>

IF YOUR SITE DOES NOT HAVE SITE SPECIFIC HIPAA USE THE FOLLOWING:

To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your "protected health information" (called PHI for short).

What protected health information will be used and shared during this study?

<INSTITUTION NAME> will need to use and share your PHI as part of this study. This PHI will come from:

- Your <INSTITUTION NAME> medical records
- Your research records

The types of information that will be used and shared from these records include:

- Laboratory test results, diagnosis and medications
- Reports and notes from clinical and research observations
- Imaging (like CT scans, MRI scans, x-rays, etc.) studies and reports
- If applicable, information concerning HIV testing or the treatment of AIDS or AIDS-related conditions, drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological conditions (but not psychotherapy notes)

Who will share, receive and/or use your protected health information in this study?

THE FOLLOWING ORGANIZATIONS MUST BE LISTED:

- Cincinnati Children's Hospital Medical Center
- Cincinnati Children's Hospital Medical Center Institutional Review Board and staff of the office of Research Compliance and Regulatory Affairs
- Cincinnati Children's Hospital Medical Center Allergy and Immunology Lab, the laboratory that will be processing your samples.
- Cincinnati Children's Hospital Medical Center Pathology Department
- Data Safety Monitoring Board for this study
- The National Institute of Allergy and Infectious Diseases (NIAID)
- National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
- Office of Rare Diseases Research (ORDR), National Center for Advancing Translational Sciences (NCATS)
- Regeneron Pharmaceuticals Incorporated

- Any agency of the federal, state or local government that regulates this research. This includes the Department of Health and Human Services (DHHS) and the Office for Human Research Protection (OHRP), NIH representatives, agents, employees, contractors and other persons assisting in conducting, monitoring or analyzing the study.
- RDCRN Data Management and Coordinating Center

How will you know that your PHI is not misused?

People that receive your PHI as part of the research are generally limited in how they can use your PHI. In addition, most people who receive your PHI are also required by federal privacy laws to protect your PHI. However, some people that may receive your PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

In this study, each participant will be assigned a unique patient identifier called a Global Unique Identifier (GUID). If you are participating in another clinical study that uses this GUID, the data for this current study could be connected to data from those other projects. Those other projects may not be about eosinophilic gastritis. Connecting data can make it more useful because it can be a more complete understanding of health because there is more information. The Global Unique Identifier (GUID) is created on a secure website by a specialized computer program that uses 12 pieces of information about you (e.g. first and last name, gender, birthday, etc.) The website and computer program used to create the GUID does not store those 12 pieces of information, but if the same information is entered again in the future, the program will return the same GUID every time. Once generated, this GUID will be used to uniquely identify you. This is how data from this study might be linked to data from another study you participate in that uses the GUID. As the GUID is generated randomly, it is impossible to identify you from the GUID string. The GUID and any identifiable information will be removed from your record before your data are shared.

You do not have to agree to have a GUID number used to participate in this research.

Can you change your mind?

You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share PHI you need to notify the study doctor, <INSERT LOCAL PI NAME & ADDRESS>, in writing. Your request will be effective immediately and no new PHI about you will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

Will this permission expire?

Your authorization to use your health information will not expire unless you revoke (withdraw) it in writing.

FUTURE USE OF YOUR DATA/BIOLOGIC MATERIALS

We are asking your permission to store DNA derived from blood, and tissue samples of biological specimens collected during the course of this study to be used in the future for tests that aren't yet planned. These tests may or may not be related to the study of eosinophilic gastrointestinal disorders.

Your stored samples will be used to obtain knowledge about genetic information in relation to your disease. Genetic tests study an individual's inherited characteristics, found in DNA, which is present in each of the cells of your body. DNA contains information needed to construct and operate the human body.

The results of tests performed on stored samples or reports resulting from the analysis of your samples will not be given to you or your doctor and they will not be put in your medical record. They will not identify you and will not affect your routine medical care.

There is no benefit to you from the storage of samples and information. However, the use of your samples and information may help researchers learn more about your disease or the genetics related to a specific condition. The purpose of storage and sharing data is to make information available for use in health research and to share what is stored with other researchers.

Collecting, storing, sharing information and making it available for other studies may help people in the future. Coded information put into databases together with other stored information from many studies conducted in different places allow researchers to study the combined information and learn even more about health and many different diseases.

Samples will be stored at *CCHMC.* If you decide to allow storage, your samples and information may be stored for an unknown length of time.

The information obtained from the research performed on your samples may in the future lead to the development of commercial products. You will not receive any money from research using your stored samples and information.

There may be unknown risks associated with the storage of samples and information. For example, if the future research involves genetic testing it is possible that it could be traced back to you because your genes are specific to you. We will make every attempt to protect your confidentiality and to make sure that your personal identity does not become known.

You can change your mind at any time and ask to have your samples destroyed. This request should be made in writing to the study doctor. If you make this request, all remaining stored samples will be destroyed. However, the results of any previous tests using your stored samples will be used. Your decision regarding the storage of samples or the information resulting from the analysis of your samples will not affect your ability to participate in this study. The future use of your samples and information may contribute to learning more about disease or help to study the genetics related to a specific condition.

Please indicate your response below for optional procedures:

I agree to the storage and sharing of samples (blood) for genetic tests not currently planned.

____Yes ____No _____

Initials of Research Subject

I agree to the storage and sharing of samples (blood and tissue) and information resulting from the analysis of my samples for other tests not currently planned.

____Yes ____No _____

Initials of Research Subject

I agree to have a GUID number used in this trial.

____Yes ____No _____

Initials of Research Subject

By signing this document, you / your child agree to participate in this research study and give permission to Cincinnati Children's to use and share you/your child's PHI for the purpose of this research study. If you refuse to sign this document you/your child will not be able to participate in the study. However, you/your child's rights concerning treatment not related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

SIGNATURES

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether you/your child should participate in this research, you will document your permission by signature below.

You will receive a copy of this signed document for your records.

_____
Printed Name of Research Participant

_____ _____
Signature of Research Participant Indicating Consent — Date

_____ _____
Signature of Parent or Legally Authorized Representative* — Date

_____
* If signed by a legally authorized representative, a description of such representative's authority must be provided

_____ _____
Signature of Individual Obtaining Consent — Date

(NOTE: This consent form with the original signatures MUST be retained on file by the principal investigator. A copy must be given to the research subject. A copy should be placed in the research subject's medical record, if applicable.)